REMARKS

This is in response to the Final Office Action of June 3, 2003, the shortened period for response there to expiring September 3, 2003. Claims 1 and 8 have been amended to more particularly set forth a unique feature of the claimed device. In particular the claimed device has a first chamber, namely a storage chamber for storing a volume of fluid to be delivered, and a second chamber, namely an outflow chamber of a smaller capacity, for delivering a fluid to the patient at a fixed rate. The fluid link between the chambers is substantially the same as the outflow from the second chamber. As a result, the claimed device provides continuous and uninterrupted delivery of fluid at a predetermined rate for days or weeks while the prior art can only demonstrate the delivery of a bolus of fluid, i.e., delivery of a preset dosage over a period of, at most a few minutes, with delivery of subsequent dosages separated from said bolus delivery by extended periods of time (ie multiple hours).

The application comprises claims 1-9. claims 1-9 were rejected under 35 USC §102(b) as being anticipated by Arzbaecher, US Patent 5,607,418 in that Arzbaecher discloses an infusion device having a variable volume storage chamber for holding the fluid to be delivered, a pressurizing means for the storage chamber to maintain the pressure in that chamber at a pressure greater then the outflow pressure, an outflow chamber for receiving the fluid from the storage chamber and maintaining that fluid at a preselected pressure, a flow restrictor between the outflow chamber and the patient and a flow regulator means between the storage chamber and the outflow chamber maintaining the pressure of the outflow chamber at a preselected pressure while allowing fluid to be transferred from the storage chamber to the outflow chamber.

It is respectfully submitted that claims 1 and B, as amended, clearly distinguishe over the cited reference and said reference neither shows nor suggests the claimed invention. US Patent 5,607,418 to Arzbaecher discloses a drug pump having two deformable fluid filled chambers which have a delivery mass flow rate below a clinically approved level when both flow means 30 and 35 are open. In order to accomplish this, the flow rate of fluid from the outer (storage) chamber 21 into the inner (output) chamber 26 is restricted to a flow rate of 1/10 to 1/150 of the flow rate of the fluid from the inner chamber to the catheter 14. This is accomplished by flow restrictors such as an extended length of narrow conduit, or orifices, or one-way valves. Arzbaecher is not capable of or intended to deliver fluid from the storage

chamber to the output chamber at the same rate as the fluid exits the output chamber or to provide continuous delivery over an extended period of time.

The Arzbaecher drug pump is not a pump for the continuous delivery of a drug over an extended period of time. It is a pump which rapidly dispenses its contents (delivery of a bolus) and then very slowly is refilled. The maximum flow rate to the patient is controlled by the pressure of the fluid in the outer (storage) chamber and the flow rate allowed by the flow restrictor between the outer chamber and the inner chamber. The flow restrictor between the inner chamber and the catheter controls the flow rate at which the bolus can be delivered to the patient. That flow rate is 10 times to 150 times greater than the flow rate of fluid into the inner (output) chamber. In order for the Arzbaecher pump to operate the inner (output) chamber must have a return bias force built into the chamber in order for it to refill after the fluid has been dispensed from that chamber. If this return bias force is not present, the chamber would not refill.

Applicant must take issue with the examiners characterization of Arzbaecher as showing a continuous deliver drug pump. One skilled in the art would clearly recognize that, based on the teachings of Arzbaecher, that patent is directed to a bolus pump for delivered descrete quantities of a fluid over a very short time period separated by an extended period of time necessary to refill the output chamber. For example, the Arzbaecher drug pump is described as delivering 4ml at a rate of 0.4ml/min, or 4ml over a period of 10 minutes. The refill rate of the output chamber is 8ml/day or 0.005ml/min (Col 4, line 45). It is capable of delivering only a 4ml bolus in no more then 10 minutes followed by a 12 hour pause. In contrast, the claimed device delivers 0.5ml - 4.0ml/hr (0.008-0.07ml/min) and refills at the same rate that it is dispensed from a large storage chamber. As an example, at these output rates and with a 200ml chamber, the claimed device is capable of continuously delivering fluid to a patient, over an extended period of time of 2800 minutes (48 hours) to 25000minutes (400+ hours) without interruption. Further, because the storage chamber can be refilled from an external source while the output chamber is delivering fluid to the chamber, the claimed device can delivery drug continuously and uninterrupted for as long as desired by the physician. The difference between these devices is not a mere variation of a prior disclosed system; it is a totally different and unique device which operates in a totally different manner not previously disclosed or suggested to provide a totally different and

unexpected result. The claimed device will continuously deliver fluid for as long as there is fluid in the storage chamber – the output chamber is never empty. The Arzbaecher pump fills and empties respectively and only delivers a dosage when the output chamber is full, even if there is fluid in the storage chamber.

Applicants' pump is a continuous flow delivery drug pump. It has a storage chamber, which is deformable, containing a fluid under a pressure higher (but adjustable by the user) then that of the outflow chamber. It also has an outflow chamber that contains fluid at a lower, closely regulated, pressure for delivery to the patient. A pressure regulator is located between the storage and outflow chambers. It is not a flow restrictor; however, it controls the fluid flowing into the outflow chamber by maintaining a constant pressure greater than than in the outflow chamber. As long as the pressure in the storage chamber is greater than the pressure in the outflow chamber, the outflow chamber will fill and will be maintained full. There is no emptying and refilling of the output chamber which must exist for the Arzbaecher drug pump to function.

The flow rate of the fluid to the patient is controlled by the regulated pressure in the outflow chamber and the flow restrictor between the outflow chamber and the catheter. If the pressure regulator between the storage chamber and the outflow chamber were kept open, as in the Arzbaecher reference, the flow rate to the patient would be significantly higher and more variable. The flow rate to the patient would depend on the pressure in the storage chamber rather than the closely regulated pressure in the outflow chamber.

The outflow chamber of the claimed invention does not empty as in the Arzbaecher drug pump because the flow of fluid from the storage chamber through the pressure regulator is the same as the flow of fluid out of the outflow chamber through the flow restrictor and into the catheter. Because of the higher pressure, it could be a greater flow but for the limiting capacity of the outflow chamber. Further, there is no dispensing valve in applicants' claimed drug pump. Once the catheter, which contains the flow restrictor, is inserted into the elastomeric septum of the drug pump, there is a continuous and uniform flow through the catheter until the pump storage container is empty. In Arzbaecher, a bolus is delivered from the outflow chamber depleting the outflow chamber contents. Flow to the patient then ceases while the outflow chamber refills, followed by another bolus delivery.

Claims 1-9 remain in the application. It is respectively submitted that these claims are patentable, fully supported by the Specification and not shown nor suggested by the cited reference. It is requested that the claims be entered as they render the application be patentable and a Notice of Allowance be issued. Alternatively, the amendment should be entered as it places the application in better form for appeal.

Respectfully submitted,

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August 18, 2003 Christina Nicoll
Date Christina Nicoll